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APR 1 0 2002

Special 510(k) Device Modification
PREMARKET NOTIFICATION
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ System with Wireless Remote Control

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
215-862-4450 PH
215-862-1009 Fax

Applicant: Laurence A. Potter

Date of Notification: January 30, 2002

2) Name of Device:

Trade Name: SurgASSIST™ System
With Wireless Remote Control

Common Name: Wireless Remote Control Unit

Classification Name: Staple, Implantable, GDW; Stapler, GAG

3) Predicate Devices:

a) SurgASSIST™ System with Circular Stapler Disposable Loading Unit with Titanium Implantable Staple, Power Medical Interventions, Inc., K003277.

b) Skylight Imaging Systems, K000908, ADAC Laboratories, Milpitas, CA 95035

c) SurgASSIST™ System with Right Angle Linear Cutter Digital Loading Unit, Power Medical Interventions, Inc., K012809.

4) Device Description:

The SurgASSIST™ Wireless Remote Control Unit is a battery powered, hand held device that transmits control commands to the SurgASSIST™ System Power Console (PC).

The existing wired Remote control version will remain as a component of the SurgASSIST System. The wireless version of the Remote Control will be commercialized in addition to the existing wired version, and sold as an accessory to the System.

A battery capable of supplying power throughout the predictive life of the Remote Control Unit is permanently installed inside the hermetically sealed case or housing. All Wireless Remote Control Units share identical transmittance frequencies, however each Unit is preprogrammed with a unique identification code. When the Wireless Remote Control Unit is used to power-on the SurgASSIST™ Power Console (PC), this unique identification code is read and stored by the Console. The Power Console, with the stored identification code will then only respond to commands sent by its corresponding Remote Control Unit.

The radio frequency commands sent via the hand-held Remote Control Unit *are Not considered Wireless Medical Telemetry, as defined by FCC.* The frequencies assigned to the transmitter will not be in Medical Telemetry MHz bands set aside by the Wireless Medical Telemetry Service (WMTS).

5) Indications For Use

The SurgASSIST™ System with Circular Stapler DLU, has applications throughout the alimentary tract for end-to-end and side-to-side anastomosis.

The SurgASSIST™ System with Right Angle Cutter Digital Loading Unit has applications in gastrointestinal, gynecological,

6) Comparison to Predicate Devices

The flowing table compares the subject device to previously cleared predicate devices:

REMOTE CONTROL PRODUCT FEATURES COMPARISON CHART

Features & Description	Power Medical SurgASSIST™ w/ Wireless RC100	Predicate Power Medical SurgASSIST™ w/ Wired RCW100	Predicate ADAC Laboratories SKYlight Imaging System
Name	SurgASSIST™ System Wireless Remote Control Unit	SurgASSIST System with Circular Stapler DLU; SurgASSIST System with Right Angle Linear Cutter	Skylight Imiging System
Manufacturer	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	ADAC Laboratories
510(k) Clearance Numbers	N/A	K003277; K012809	K000908
Product Code	RC100	RCW100 *(RCWW was in original K003277submission)*	Unknown if this component is sold separately
Intended use	Applications throughout the alimentary tract for end to end, end to side, and side to side anastomosis	Applications throughout the alimentary tract for end to end, end to side, and side to side anastomosis	Skylight is intended to produce images depicting the anatomical distributions of single photon and positron emitting radioisotopes within the human body for interpretation by medical personnel.
FDA Class	II	II	II
Human Factors	Handheld, wireless, pushbutton radio frequency command	Handheld, pushbutton command, with 3 meter silicone coated wire for connection to SurgASSIST Power Console (PC)	Handheld, wireless, pushbutton command
Size	16 cm x 9.5cm	16 cm x 9.5 cm with 3 meter attached cord	No details available
Housing Material	ULTEM polyether-imide	polycarbonate	Plastic
Keypad Material	Parylene coated Silicone Rubber	Parylene coated Silicone Rubber	No details available
Command Buttons	"ON" "FIRE" "Release" "OPEN" "CLOSE" Directions "North" "South" "East " " West"	"ON" "FIRE" "Release" "OPEN" "CLOSE" Directions "North" "South" "East " " West"	No details available
Transmitter / Receiver	RF Transmitter in hand held remote. Receiver in Power Console (PC)	Contains indicators for appropriate range for desired closed staple height, but can be deployed out of range	Will not deploy until the anvil/cartridge gap is within a certain range on a built in indicator
Power	Battery powered. High Temperature lithium AA Cell 3.8 VDC, 1.6Ah	None	Presumably battery powered. No details available
Software Containing	Yes	No	No details available
Sterilization Methods	Supplied to Customer Non-Sterile Steam Autoclave Compatible Ethylene Oxide Compatible Peracetic Acid Wash Compatible	Supplied to Customer Non-Sterile Ethylene Oxide Compatible Peracetic Acid Wash Compatible	No details available
How Supplied	Non-Sterile, plastic wrapped in single unit corrugated box	Non-Sterile, plastic wrapped in single unit corrugated box	No details available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2002

Mr. Laurence A. Potter
Vice President, Regulatory Affairs
and Quality Assurance
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938

Re: K020343
Trade/Device Name: SurgASSIST™ System with Wireless Remote Control
Regulation Number: 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: March 8, 2002
Received: March 11, 2002

Dear Mr. Potter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K 020343

Device Name: *SurgASSIST™ System with Wireless Remote Control*

INDICATIONS FOR USE: (Note: The intended use for this product modification will be substantially identical to that of Power Medical Interventions, Inc. immediate predicate 510(k) Notification's, K003277 & K012809).

The SurgASSIST™ System with Circular Stapler DLU, has applications throughout the alimentary tract for end-to-end and side-to-side anastomosis.

The SurgASSIST™ System with Right Angle Cutter Digital Loading Unit has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomosis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X OR Over-The-Counter Use _____
Per 21CFR §801.109

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020343